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Carole Cifrino
Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333

RE: Mylan Inc. comments on "Implementing Product Stewardship in Maine: 2011 Report to the Joint Standing Committee on Natural Resources"

Dear Ms. Cifrino:

Thank you for the opportunity to comment on the Maine Department of Environmental Protection (DEP) report "Implementing Product Stewardship in Maine: 2011 Report to the Joint Standing Committee on Natural Resources." Mylan Inc. is one of the world's leading generics and specialty pharmaceutical companies and is the largest manufacturer of generic pharmaceuticals that is headquartered in the United States. We currently provide products to domestic customers and those in more than 140 countries and territories. As a concerned stakeholder, we would like to provide you with feedback on the recommendations made in this report.

While we share the goal of protecting Maine's environment and reducing illegitimate access to pharmaceuticals, we are very concerned that the legislation proposed by DEP will provide little or no results at a very great cost. Even proponents of the product stewardship concept for drugs have stated that the overwhelming majority of pharmaceuticals in the environment are not the result of unused drugs, but are instead the result of human or animal excretion. Science cannot quantify what portion of the trace amounts of pharmaceuticals in the environment are the result of unused drugs, but scientists who have testified on this issue have generally agreed that unused drugs are only a small fraction. We have very serious concerns about the proposed legislation and especially its impact on the cost availability of affordable generic pharmaceuticals.

Generics are currently almost 75% of prescription drugs dispensed in the United States yet generics account for only 22% of the dollars spent on pharmaceuticals overall. If a program such as the one proposed becomes law, it would result in a significant increase in cost of doing business in Maine. In the case of generics, many prescription drugs are commodity products that sell for pennies per pill, and the cost of the proposed product stewardship program could easily outstrip the manufacturer's entire price for the product.

The marketplace for generic drugs is vastly different and more complicated than for brand products. Generics manufacturers operate within a hyper competitive market with multiple companies offering the same products and prices intensely negotiated with purchasers. While this results in a tremendous savings for consumers, the government and the healthcare system, extreme competition leaves only razor thin profit margins for generic manufacturers and no room to fund a program such as the one proposed by DEP. This is especially true if a fee to cover the cost of collection and disposal of unused drugs cannot be added at the point of sale or collection. As a result, such a program would almost certainly result in higher prices for generic drugs in Maine and increased spending on pharmaceuticals for consumers, business and the State.

If participation in a competitive market is reduced by one or more companies that are unable to sustain business activity in Maine due to the cost of such a program, the rules of supply and demand would also predict price increases across the board.

Maine achieves significant savings through utilization of generic drugs in state programs. The proposed legislation could undermine those savings and raise the cost of health care in Maine. At a time when Maine and other states are working to reduce spending on health care, the proposed legislation would likely increase costs to consumers, government and the entire healthcare system. This would not be a good outcome for Maine particularly when there is no evidence that the proposed take-back program would provide measureable and/or desired benefits.

While the concept of “product stewardship” programs has a great appeal for many, we respectfully suggest that unused drugs are a very different waste product to manage as compared to rechargeable batteries, electronic waste, mercury thermometers, etc. Firstly, drugs cannot be recycled as envisioned by stewardship for other products. Secondly, the number of manufacturers of products that would be subject to the proposed legislation and the number of consumers who are “residential generators” makes this a massive effort and a much more complicated take-back proposal than any ever attempted. Thirdly, pharmaceuticals are one of the most heavily regulated products in America and those regulations – particularly with regard to controlled substances – could make a take back program extremely difficult to design and potentially very expensive to operate. Congress has directed the U.S. Drug Enforcement Administration to consider rules that would allow for take-back of controlled substances but that process is not complete and it is unclear what the outcome will be.

At least some manufacturers currently have processes to take back undispensed and expired drugs from pharmacies. While that effort is small in scope when compared to the proposed consumer take-back program and addresses only drugs that were never dispensed by pharmacies, it does provide us with some basis of understanding of the costs involved with such efforts. In the case of Mylan, our program cost approximately 75 cents per unit (bottle or package) returned for processing and disposal. We believe it would be significantly more expensive to operate a program to take back drugs from the consumers since the cost of our pharmacy program does not include shipping from the pharmacy, promotion of the program to consumers, law enforcement to oversee handling of controlled substances, and many other costs which are not now known.

While some proponents have pointed to a program in British Columbia as a model, there are significant differences in that program that make it much less expensive than the Maine proposals and an improper comparison. British Columbia relies on a voluntary pharmacy-based take-back program and Canada does not differentiate between handling of controlled substances and other drugs. A pilot program conducted in the State of Maine may be a better gauge of the potential cost of the program that would be required by DEP’s proposal than either the British Columbia program or Mylan’s current program for disposing of undispensed and expired drugs taken back from pharmacies. The Maine pilot used mail back as the collection method in order to comply with U.S. Drug Enforcement Administration rules on handling of controlled substances. The directors of Maine’s pilot have reported a cost of \$5 to \$7 per returned drug due to special envelopes, postage, law enforcement involvement in the collection and storage of returned drugs, etc. Many generic drugs are only pennies a pill and even \$5 for a returned drug would be significantly more than the cost that a manufacturer receives for many products.

It’s well known that certain large retailers sell generic drugs at very low prices compared to brand drug prices (e.g., Wal-Mart’s \$4 program for a 30 day supply of many widely dispensed generics). It should come as no surprise that manufacturer’s wholesale prices are often considerably lower than the prices charged by pharmacies.

Imposing a program that added costs of this magnitude to generic drugs would make it difficult, if not impossible, for a generic manufacturer to continue to sell many of the low cost drugs that the people of Maine rely on. Generic manufacturers simply cannot afford to pay more to take back a bottle

of pills than we sold it for in the first place. This substantial additional cost would have to be passed on to consumers, either directly by the pharmacies as surcharges or indirectly in the form of price increases by the manufacturers. If manufacturers do not succeed in passing along the costs through price increases or surcharges and are forced to absorb the extra cost, then this law could make selling many generic products into Maine untenable. This is especially true in the case of high volume low margin generic drugs, of which there are many. These are also the products where Maine consumers enjoy the greatest savings and value.

Since there is no national approach or consensus yet on this issue, by passing this law, Maine would be distinguishing itself in a negative way because it would be relatively straightforward for manufacturers to label their products as "not for sale in Maine." If these drugs are withdrawn from the state -- especially widely dispensed, commodity generics -- there could be significant unintended consequences on patient access to important medicines and dramatically increased costs to consumers. We believe that neither of those options is good for the people of Maine and we urge the Legislature not to force companies to make those choices.

DEP has also proposed the creation of a separate program for collection of "unwanted medical sharps." We have concerns about this new proposal as well -- in part because of the lack of discussion with industry on the issue prior to the department's recommendation and uncertainties about how such a program might be structured. To our knowledge, DEP had not reached out to manufacturers or distributors of medical sharps before making this proposal. We have a significant interest in this proposal because a subsidiary of Mylan distributes a product that could be affected by this proposal.

We respectfully oppose DEP's proposal. We urge the Legislature to reject the take-back proposal as currently written again this year. Mylan would welcome an opportunity to work with other concerned parties to consider options that could address the goal of providing Maine consumers with alternatives for disposal of unused medicines without adding to the cost of affordable generic prescription drugs.

Thank you for the opportunity to share our concerns.

Sincerely,



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